

# PACKAGE INSERT

## Boston® Orthokeratology (oprifocon A) Shaping Lenses

FOR  
OVERNIGHT WEAR  
FOR

## Bausch & Lomb Vision Shaping Treatment™

### IMPORTANT

Please read carefully and keep this information for future use.

This package insert is intended for the eye care practitioner, but should be made available to patients upon request. The eye care practitioner should provide the patient with the patient instructions that pertain to the patient's prescribed lens.

**CAUTION: Federal law restricts this device to sale by, or on the order of a licensed practitioner.**

Boston Orthokeratology (oprifocon A) Shaping Lenses should be fitted only by a contact lens fitter trained and certified in the fitting of conventional (non-reverse geometry) and reverse geometry contact lenses.

**Nonsterile. Clean and condition lenses prior to use.**

### DESCRIPTION

Boston Orthokeratology (oprifocon A) Shaping Lenses are lathe cut contact lenses with spherical posterior surfaces in blue, green, red and yellow tinted versions. The posterior curve is selected to properly fit an individual eye for orthokeratology and the anterior curve is selected to provide the necessary optical power for a temporary reduction of myopia. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

Boston Orthokeratology (oprifocon A) Shaping lenses are made from Boston® Equalens®II (oprifocon A) polymer with a water content of less than 1 percent. The material contains an ultraviolet absorber, Uvinul D-49. The blue tinted lenses contain D&C Green #6 as a color additive. The green tinted lenses contain D&C Green #6 and D&C Yellow #18. The red tinted lenses contain D&C Red #17 as a color additive. The yellow tinted lenses contain D&C Yellow #18 as a color additive.

### LENS PARAMETERS AVAILABLE

Chord Diameter	9.6mm to 11.6mm
Center Thickness	
For low minus lens	0.20mm to 0.32mm
For plus lenses	0.20mm to 0.32mm
Base Curve	7.30mm to 10.15mm
Reverse Curve	5.0 to 9.0 mm. Steeper than the base curve in proportion to the amount of correction
Alignment Curve 1	7.0 to 9.0 mm. Steeper than the base curve but flatter than the Reverse curve. Generally equal to the Flat K of the cornea being fit.
Alignment curve 2	7.25 to 9.25 mm. Steeper than the base curve but flatter than AC1 and Reverse curve.
Peripheral curves	9.00mm to 15.00mm
Back Vertex Power	+1.50 to -5.00 Diopters



Figure 1: Representation of the reverse geometry lens design.

### PHYSICAL PROPERTIES

The physical properties of oprifocon A

Refractive index	1.423
Light Absorbance (absorbance units/inch)	
Blue(640nm)	10.0
Green(640nm)	4.8
Yellow(420nm)	10.3
Red(525nm)	2.5
Wetting Angle	30 degrees by Captive Bubble
Specific Gravity	1.24
Hardness	114 Rockwell
Water Content	less than 1%
Oxygen Permeability	85 by Iso/Fatt

### ACTIONS

The Boston Orthokeratology (oprifocon A) Shaping Lens produces a temporary reduction of myopia by changing the shape (flattening) of the cornea, which is elastic in nature. Flattening the cornea reduces the focusing power of the eye, and if the amount of corneal flattening is properly controlled, it is possible to bring the eye into correct focus and completely compensate for myopia.

The posterior surface of regular contact lenses generally aligns with the central cornea and rests directly on the corneal tear layer. Regular contact lenses are designed to cause little or no effect on the cornea but Boston Orthokeratology (oprifocon A) Shaping lenses are designed to purposely flatten the shape of the cornea by applying slight pressure to the center of the cornea when the patient is asleep.

After the lens is removed, the cornea retains its altered shape for all or most of one's waking hours. The lenses are designed to be worn overnight with removal during the following day. The Boston Orthokeratology (oprifocon A) Shaping Lenses must be worn at night on a regular schedule to maintain the orthokeratology effect, or the myopia will revert to the pretreatment level.

### INDICATIONS

Boston Orthokeratology (oprifocon A) Shaping Lenses for Overnight Wear are indicated for use in the reduction of myopic refractive error in non-diseased eyes. The lenses are indicated for overnight wear as part of the Bausch & Lomb Vision Shaping Treatment™ process for the temporary reduction of myopia up to 5.00 diopters with eyes having astigmatism up to 1.50 diopters. The lenses may only be disinfected using a chemical disinfection system.

Note: To maintain the Orthokeratology effect of myopia reduction, overnight lens wear must be continued on a prescribed schedule. Failure to do so can affect daily activities (e.g., night driving), visual fluctuations and changes in intended correction.

### CONTRAINDICATIONS (REASONS NOT TO USE)

**DO NOT USE** the Boston Orthokeratology (oprifocon A) Shaping Lenses when any of the following conditions exist:

- Acute and sub-acute inflammations or infection of the anterior chamber of the eye.
- Any eye disease, injury, or abnormality that affects the cornea, conjunctiva or eyelids.
- Severe insufficiency of tears (dry eyes)
- Corneal hypoesthesia (reduced corneal sensitivity).
- Any systemic disease which may affect the eye or be exacerbated by wearing contact lenses.
- Allergic reactions of ocular surfaces or adnexa which may be induced or exaggerated by wearing contact lenses or use of contact lens solutions.
- Allergy to any ingredient, such as mercury or thimerosal, in a solution which is to be used to care for your Boston Orthokeratology (oprifocon A) Shaping Lenses.
- Any active corneal infection (bacterial, fungal or viral).
- If eyes become red or irritated

### WARNINGS

The practitioner should provide this warning to the patient.

#### PROBLEMS WITH CONTACT LENSES AND LENS CARE PRODUCTS COULD RESULT IN SERIOUS INJURY TO THE EYE.

It is essential that the patient follows the directions of the eye care practitioner and all labeling instructions for proper use of contact lenses and lens care products.

Eye problems, including corneal ulcers, can develop rapidly and lead to loss of vision; if the patient experiences:

- Eye Discomfort,
- Excessive Tearing,
- Vision Changes,
- Loss of Vision,
- Redness Of The Eye,
- Or Other Problems with their Eyes,

THEY SHOULD BE INSTRUCTED TO IMMEDIATELY REMOVE THE LENSES, AND PROMPTLY CONTACT THEIR EYE CARE PRACTITIONER.

The risk of ulcerative keratitis has been shown to be greater among wearers of extended wear lenses than among wearers of daily wear lenses. The risk among extended wear lens wearers increases with the number of consecutive days that lenses are worn between removals, beginning with the first overnight use. This risk can be reduced by carefully following directions for routine lens care, including cleaning the storage case. Additionally, smoking increases the risk of ulcerative keratitis for contact lens wearers. It is recommended that contact lens wearers see their eye care practitioners twice each year or, if directed, more frequently.

Boston Orthokeratology (oprifocon A) Shaping Lenses are to be worn overnight with removal during all or part of each following day. Wearing the lenses continuously (extended wear) presents increased risk, which increases with the number of consecutive days that the lenses are worn between removals. Although the Bausch & Lomb Vision Shaping Treatment process prescribes only overnight wear with removal during waking hours, and although the safety risks of overnight wear with removal upon waking may not be as great as with extended wear, there is still increased risk beginning with the first overnight period.

### PRECAUTIONS

#### Eye Care Practitioner

Clinical studies have demonstrated that Boston Orthokeratology (oprifocon A) Shaping Lenses are safe and effective for their intended use. However, the clinical studies may not have included all design configurations or lens parameters that are presently available in the material. Consequently, when selecting an appropriate lens design and parameters, the eye care practitioner should consider all factors that affect lens performance and the patient's ocular health; including oxygen permeability, wettability, central and peripheral thickness, and optic zone diameter.

The safety and effectiveness of the Boston Orthokeratology (oprhocon A) Shaping Lenses **have not** been clinically studied in adolescent and pediatric subjects.

The potential impact of these factors on the patient's ocular health should be weighed against the patient's need for refractive reduction; therefore, the continuing ocular health of the patient, and lens performance on the eye should be carefully monitored by the prescribing eye care practitioner.

Boston Orthokeratology (oprhocon A) Shaping Lenses are supplied non-sterile in an individual plastic case. The lens is shipped dry and must be cleaned and conditioned prior to use.

### Patient

Patients should be informed of the following precautions

#### Solution Precautions

- Different solutions cannot always be used together, and not all solutions are safe for use with all lenses. Use only recommended solutions with the shaping lenses.
- Do not heat the wetting/soaking solution and lenses.
- Always use fresh unexpired lens care solutions.
- Always follow directions in the package inserts of the contact lens solutions used.
- Use only a chemical lens care system. Use of a heat (thermal) lens care system can cause damage by warping Boston Orthokeratology (oprhocon A) Shaping Lenses.
- Sterile unpreserved solutions, when used, should be discarded after the time specified in the labeling directions.
- Do not use saliva or anything other than the recommended solutions for lubricating or wetting lenses.
- Always keep the lenses completely immersed in the recommended storage solution when the lenses are not being worn (stored).

#### Handling Precautions

- Always wash and rinse hands before handling lenses. Do not get cosmetics, lotions, soaps, creams, deodorants, or sprays in the eyes or on the lenses. It is best to put on lenses before putting on makeup. Water-base cosmetics are less likely to damage lenses than oil-base products.
- Be certain that your fingers or hands are free of foreign material before touching your contact lenses. Microscopic scratches of the lenses may occur, causing distorted vision and/or injury to the eye.
- Carefully follow the handling, insertion, removal, cleaning, disinfecting, storing and wearing instructions in this booklet and those prescribed by your eyecare practitioner.
- Always handle your lenses carefully and avoid dropping them.
- Never use tweezers or other tools to remove your lenses from the lens container unless specifically indicated for that use. Pour your lens into your hand.
- Do not touch the lens with your fingernails.
- To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.

#### Lens Wearing Precautions

- CAUTION: Nonsterile. Clean and condition lenses prior to use.
- If the lens sticks (stops moving) on the eye, follow the recommended directions on Care for a Sticking Lens in the "Instructions for Wearers" booklet. The lens should move freely on the eye for the continued health of the eye. If non-movement of the lens continues, you should immediately consult your eye care practitioner.
- Never wear your contact lenses beyond the period recommended by your eye care practitioner.
- Avoid, if possible, all harmful or irritating vapors and fumes when wearing lenses.
- If aerosol products such as sprays are used while wearing lenses, exercise caution and keep eyes closed until the spray has settled.

#### Lens Case Precautions

- Contact lens cases can be a source of bacterial growth. To prevent contamination and to help avoid serious eye injury, always empty and rinse the lens case with fresh, sterile rinsing solution and allow to air dry.
- Lens cases should be replaced at regular intervals as recommended by the lens case manufacturer or eyecare practitioner.

#### Discuss these topics with each patient:

- Wear of contact lenses during sporting activities
- Use of any medication in your eye
- Importance of adhering to the recommended follow-up schedule to assure the continuing health of your eyes.
- Informing your doctor (health care practitioner) about being a contact lens wearer
- Informing your employer of being a contact lens wearer. Some jobs may require the use of eye protection equipment or may require that you not wear contact lenses during work hours.
- What should be done if vision is inadequate during the day.

## ADVERSE EFFECTS (PROBLEMS AND WHAT TO DO)

Patients should be informed that the following problems might occur:

- Eyes stinging, burning, itching (irritation), or other eye pains.
- Comfort is less than when lens was first placed on eye.
- Feeling of something in the eye, such as a foreign body or scratched area.
- Excessive watering (tearing) of the eyes
- Unusual eye secretions
- Redness of the eyes
- Reduced sharpness of vision (poor visual acuity)
- Blurred vision, rainbows, or halos around objects
- Sensitivity to light (photophobia)
- Dry eyes

Please refer to the Clinical Study Section of this package insert for adverse effects observed during the study.

If the patient notices any of these conditions, the patient should be instructed to **IMMEDIATELY REMOVE THE LENSES**.

The patient should be advised to follow these instructions:

- If the discomfort or problem stops, then look closely at the lens.
- If the lens is in any way damaged, DO NOT put the lens back on the eye. Place the lens in the storage case and contact the eye care practitioner.
- If the lens has dirt, an eyelash, or other foreign objects on it, or the problem stops and the lens appears undamaged, thoroughly clean, rinse and disinfect the lens; then reinsert it.
- If the problem continues, IMMEDIATELY remove the lenses and consult the eye care practitioner.

When any of the above problems occur, a serious condition such as infection, corneal ulcer, neovascularization, iritis, persistent stromal edema or GPC (giant papillary conjunctivitis) may be present. The patient should be instructed to keep the lens off the eye and seek immediate professional identification of the problem and prompt treatment to avoid serious eye damage including corneal scarring, opacification, blindness or loss of eye.

## CLINICAL STUDY DATA

### Demographic Information

A total of 378 eyes (191 patients) were enrolled in the clinical study with 264 eyes (134 patients) completing a minimum of 9 months of contact lens wear. Data on 210 eyes (eyes with more complete effectiveness data) were analyzed for safety and effectiveness after 9 months of wear (the "core" group). In addition to this core group, 54 eyes were analyzed for safety data (the "adjunct" group). The entire population consisted of 128 females and 63 males, ranging in age from 17 to 64.

### Effectiveness Outcomes

The average amount of myopia that can be expected to be corrected is shown in the following table. These values are only averages and some patients can be expected to achieve more or less than these averages.

Average Reduction in Myopia (Diopters)  
(210 Core Eyes)

Initial Myopia	Mean Reduction (D)	Mean Residual (D)
0 to -1.00	1.15	0.21
> -1.00 to -2.00	1.52	-0.15
> -2.00 to -3.00	2.39	-0.13
> -3.00 to -4.00	3.29	-0.22
> -4.00 to -5.00	3.85	-0.57
> -5.00 to -6.00	4.67	-0.68
> -6.00	4.88	-1.25

### Uncorrected Visual Acuity (UCVA)

The primary efficacy endpoint for the core group was the number of eyes achieving **at least 2 lines of improvement in uncorrected visual acuity with at least 20/40 vision**. For the 210 Core eyes available at 9 months, 199 eyes (95%) met these criteria of success, while 11 eyes did not achieve this successful outcome.

PRIMARY EFFICACY ENDPOINT AT 9 MONTHS  
STRATIFIED BY PRE-TREATMENT MYOPIA  
CORE EYES (210)

	PRE-TREATMENT MYOPIA (MRSE)							Total
	0 to -1.00*	<-1.00 to -2.00	<-2.00 to -3.00	<-3.00 to -4.00	<-4.00 to -5.00	<-5.00 to -6.00	<-6.00 to -7.00	
n	n	n	n	n	n	n	n	n
A. #eyes at 9 months with 2 lines improvement and 20/40 or better	5	60	72	34	22	5	1	199
B. #eyes at 9 months not meeting above criteria, data available	1	3	4	0	3	0	0	11
C. #eyes enrolled and available at 9 months	6	63	76	34	25	5	1	210
% eyes at visit with Acuity Success* (A/Dx100)	83.3	95.2	94.7	100.0	88.0	100.0	100.0	94.8
MRSE	Mean	0.21	-0.15	-0.13	-0.22	-0.57	-0.68	-1.25
	Std. Dev	0.17	0.64	0.50	0.51	1.14	0.68	0.0

\*only 1 eye had an MRSE <-1.00 (0.63)

Post-treatment visual acuity was assessed on the 210 analyzed core eyes. Seventy-three percent achieved 20/20 or better, 95% achieved 20/40 or better.

### Accuracy

At 9-months, 80 percent of the core eyes achieved a reduction of myopia to within 0.50 D of target and 93% achieved a reduction to within 1.00 D of target. The accuracy of the temporary reduction in myopia is given in the following table, which also shows the final acuity without lenses. However, accuracy of correction is less with correction higher than 4.00D than with those less than 4.00D.

VISUAL OUTCOME ACCURACY OF THE  
TEMPORARY REDUCTION OF MYOPIA,  
FINAL ACUITY WITHOUT CONTACT LENSES  
(Core Eyes at 9-Months)

Initial Myopia**	% Within 0.50D of Target*	% Within 1.00D of Target*	% With Final VA 20/20 or better*	% With Final VA 20/40 or better*
<0 to -1.00D	100%	100%	100%	100%
-1.25 to -2.00D	81%	93%	82%	94%
-2.25 to -3.00D	87%	96%	77%	94%
-3.25 to -4.00D	79%	94%	71%	100%
-4.25 to -5.00D	60%	88%	64%	95%

\*100x# reported/# in category

\*\* Manifest Refraction Spherical Equivalent

### Wearing Time

The lenses were intended for overnight wear only. The average wear time was reported to be between 8 and 10 hours per night, and there was no apparent relationship between the number of hours of wear and the visual outcome, for any amount of pretreatment myopia.

### Analysis of Post Lens Removal Uncorrected Visual Acuity (UCVA) Regression

The effects of wearing your lenses at night are not permanent and slowly diminish after you remove your lenses. While this does not present a problem for most wearers, it is important to realize for some patients their vision at the end of the day may not be fully satisfactory for highly demanding visual tasks. Although this may not be an issue for most wearers, the eye care practitioner should consider each patient's "late in the day" circumstance to discuss what steps the patient should take if this is a concern.

The data collected during the clinical study for the regression of UCVA following lens removal were incomplete.

A postapproval study to evaluate the stability of treatment post lens removal will be conducted.

### Effects on Astigmatism

Either increases or decreases in astigmatism may occur following orthokeratology. Of the 210 analyzed eyes, 35% showed no change in refractive astigmatism, 41% showed a decrease of one diopter or less, 2% showed a decrease greater than one diopter, 20% showed an increase of one diopter or less, and 2% showed an increase greater than one diopter.

## OVERNIGHT WEAR SAFETY SUMMARY

In this study all eyes were evaluated for safety of overnight wear for orthokeratology to treat myopia and myopia with astigmatism. Two hundred and sixty-four eyes were followed for 9 months. The data on best corrected acuity, adverse events, slit lamp findings and symptoms provide reliable indications of the safety of oprrhocon A in this treatment modality.

### Best Spectacle Corrected Visual Acuity (BSCVA)

The majority of core eyes (those eyes with more complete effectiveness data upon which the primary effectiveness determinations can be made), 73% had no change in BSCVA from baseline. 18% had a gain of 1 line, <1% had a gain of 2 lines, and 1% had a gain of >2 lines in BSCVA as compared to baseline. Concurrently, 8% had a loss of >1 line as compared to baseline. No core eyes had a loss of  $\geq 2$  lines of BSCVA.

For the 54 completed adjunct eyes (those subjects for which incomplete data was collected but enough data is provided to use as safety data) the change in lines of BSCVA at the 9-month post-treatment interval showed 41% had no change in BSCVA from baseline, and 1% gained 1 line. There were 4% with loss of 1 line in BSCVA. Data were not reported for 29 eyes.

When considering all eyes entered into the study, there were a total of 42 incidents (in 34 eyes) of at least a temporary reduction of  $\geq 2$  lines of BSCVA during the course of the study. Only 12 of the 42 incidents occurred after 3 months. Duration of the vision loss was not accurately determined in all cases, but for incidents in which there is some documentation and recovery was demonstrated, length of time to documented recovery varied from 1 day to 9 months. Thirty-three eyes had a duration of reduced vision of  $> 7$  days.

Four eyes in 3 patients showed a reduction of  $\geq 2$  lines of best corrected acuity from initial visit to last study visit. One of these eyes was subsequently documented to return to normal acuity. No significant ocular abnormalities were observed in these eyes with biomicroscopy at the time of study exit.

#### Slit Lamp Findings

For 2,907 eye exams, there were 14 exams showing slit lamp findings greater than grade 2 reported as follows: grade 3 for staining (3 incidents); grade 4 for staining (2 incidents); grade 3 for injection (2 incident); grade 3 "other" (4 incidents); and ungraded (3 incidents: 2 staining and 1 tarsal abnormality). All findings greater than grade 2 resolved without further complications. There were 5 slit lamp findings  $> 2$  Grade 2 or ungraded, in the Core, and 9 in the adjunct. The most significant of the  $> 2$  Grade 2 findings, were 3 Grade 3 Corneal Staining cases, 2 Grade 4 Corneal Staining cases, 1 case of Corneal Infiltrates (grade 3) and 2 Cases (2 eyes of 1 subject) of trace Iritis.

#### Symptoms, Problems and Complaints

Subjects were asked to report symptoms and complaints at each follow-up visit. For core and completed adjunct eyes, poor distance vision was reported for 17% (389/2389), flare or ghosting were reported for 9% (216/2389), and all other symptoms (poor near vision, red eye, excessive lens awareness/pain, excessive discharge, burning/itching, and photophobia) were reported for 8% (188/2389) throughout the study. It appears that the eyes with initial myopia above 3.00D had a higher incidence of these visual disturbances.

#### Discontinuations

Of the 90 adjunct subjects, 55 subjects (110 eyes) discontinued before completing 9 months of wear, for reasons as listed in the following table.

REASONS FOR DISCONTINUATION		
<i>Clinical Reason*</i>	<i>#eyes</i>	<i>% of all eyes</i>
Unacceptable vision	52	14%
Lack of Comfort	28	8%
Unacceptable physiology	12	3%
<i>Non-clinical Reason</i>		
Lost-to-follow-up	38	10%
Other **	10	3%

\*Several subjects reported more than 1 reason for discontinuation, without giving any priority to the reasons.  
 \*\*Other\* included returned to spectacles (2 eyes), night vision bothered (2 eyes), wanted prior uncorrected near vision (2 eyes), financial (2 eyes), and could not maintain visit schedule (2 eyes).

#### Adverse Events and Complications

There were 12 significant lens-related adverse events reported in 10 subjects. Two eyes had bilateral grade 4 staining with significant decrease in vision to 20/80. One eye had grade 3 corneal staining secondary to a dislodged lens. One eye had significant corneal distortion with reduced vision to 20/200 and rippling on the cornea. Two eyes had bilateral Iritis with trace cells and flare in both eyes. One eye had corneal infiltrates.

Two eyes had abrasion (grade 3 staining). One eye had reduction of BSCVA to 20/50 secondary to a decentered lens. One eye had reduction of BSCVA to 20/60 due to central staining. One eye had reduction of BSCVA to 20/60 with no reason given.

All of these eyes that showed acuity reductions were documented as returning to normal vision, except two eyes of one subject with severe corneal staining that showed 2 lines loss of BSCVA. The return to pretreatment VA was not recorded on the case report form of this subject although the subject returned to soft contact lens wear and verbally reported that vision was normal. Of the 10 subjects for which adverse events were reported, 4 subjects discontinued the study. All adverse events resolved without further complications.

#### Change in Corneal Cylinder

The reduction in refractive error and improvement in unaided visual acuity is the result in part of a change in the corneal radius as measured by keratometry. The keratometer measures the corneal curvature in the two principal meridians at a chord diameter slightly less than 3 millimeters. The keratometer does not provide data of the local curvature inside or outside of the location of its measurement.

14% of all treated eyes manifested more than one diopter of increase in corneal cylinder from baseline to the ninth month visit. The core group contained 26 eyes with greater than 1 D increase and the adjunct group contained of 24 eyes with greater than 1 D increase.

There were 7 eyes in the core group and 11 in the adjunct group that had increases (initial to patient's last visit) in corneal cylinder of  $> 2$  D. No eye with cylinder increase  $> 1$  D had a BSCVA at exit worse than 20/30.

#### Summary of Key Safety Variables

A summary of key safety variables is presented in the following table

SUMMARY OF KEY SAFETY VARIABLES		
<i>Criteria</i>	<i>All Treated Eyes (364)</i>	
	<i>n</i>	<i>%</i>
Significant Adverse Events	12*	3
Loss of $\geq 2$ lines BSCVA†‡	4	1
BSCVA worse than 20/40†	1	<1
Increase of $> 1$ D Refractive Cylinder†	12	3
Increase of $> 1$ D Corneal Cylinder†	50	14

\*Includes 4 discontinued subjects (6 eyes).

† from baseline to exit visit

‡ there were 42 incidents (in 34 eyes) of at least a temporary reduction of  $\geq 2$  lines of BSCVA during the course of the study. All except 4 discontinued eyes were documented as returning to normal during the study; one eye was documented to return to normal acuity after the study. No significant ocular abnormalities were observed in these eyes with biomicroscopy at the time of study exit.

#### FITTING

Caution: Boston Orthokeratology (oprifocon A) Shaping Lenses should be fitted only by a contact lens fitter trained and certified in the fitting of conventional (non-reverse geometry) and reverse geometry contact lenses.

Conventional methods of fitting rigid contact lenses for orthokeratology DO NOT APPLY to the Boston Orthokeratology (oprifocon A) Shaping Lenses. For a description of fitting techniques, refer to the Fitting Guide for Boston Orthokeratology (oprifocon A) Shaping Lenses for Overnight Wear for Bausch & Lomb Vision Shaping Treatment; copies of the Fitting Guide are available from:

Polymer Technology, a Bausch & Lomb company  
 1400 North Goodman Street  
 Rochester, New York 14609  
 1 (800) 333-4730

## RECOMMENDED WEARING SCHEDULE

Although many practitioners have developed their own initial wearing schedules, the following sequence is recommended as a guideline. Patients should be cautioned to limit the wearing schedule as recommended by their eye care practitioner regardless of how comfortable the lenses feel.

Wearing Schedule: On night one lenses should be inserted at a time early enough to achieve 8 to 10 hours of closed eye wearing time (sleep). A well fit lens provides for centration with the eye closed. The effects of lid interaction on blinking and gravity may result in lens decentration during open eye wear. The patient should place the lens(s) in their eye 15 to 20 minutes before going to sleep.

Be aware "when in doubt, take it out". It is important that the new wearer not sleep in a lens that has a significant foreign body sensation. In the event of foreign body sensation, instruct the patient to remove the lens, clean and re-wet it; and again place the lens in the eye. If the sensation continues, remove the lens. The lens should not be worn.

Appointment Schedule: The patient should report for follow-up evaluation the morning after the first overnight wear. The visit is best scheduled within a few hours of awakening and the patient should report with lenses in place. This visit provides an excellent opportunity to evaluate lens centration and potential lens adherence.

Upon the absence of clinical signs and complications, the patient may be instructed to continue overnight wear of the lenses until the next scheduled follow-up visit.

An alternate daytime wear schedule may be offered at the practitioner's discretion.

#### Myopic Reduction Maintenance Lens (Retainer Lens) Schedule

After a period of several days, or when the eyecare practitioner is satisfied that the patient has adapted to the Boston Orthokeratology (oprifocon A) Shaping lenses, the eyecare practitioner may optimize the wearing schedule for an individual patient to monitor the duration of visual improvement. This may continue as long as the patient can see clearly. When it is found that the patient experiences a visual decrement following lens removal, the schedule of overnight wear must be modulated to maintain visual performance.

## LENS CARE DIRECTIONS

The lens care products listed below are recommended by Bausch & Lomb Incorporated for use with the Boston Orthokeratology (oprifocon A) Shaping lenses.

#### Chemical Lens Care System

##### Two Bottle System:

Boston ADVANCE® Cleaner or Boston® Cleaner

Boston ADVANCE® Comfort Formula Conditioning (soaking) Solution or Boston® Conditioning Solution

OR

##### One Bottle System:

Boston SIMPLUS™ Multi-Action Solution (Removes Protein, Cleans, Disinfects, Conditions, Cushions).

The directions found in the package inserts from these products should be followed. Failure to adhere to these procedures may result in the development of serious ocular complications. A patient should not switch from one care system to another unless it has been determined by the eye care practitioner that this is necessary. Do not mix or alternate the disinfection and storage systems unless so indicated on the product label.

Inform the patient of the following lens care suggestions:

- Always wash and rinse your hands before handling your shaping lenses
- Never use tweezers or other tools to remove your lenses from the lens container. Pour the lens into your hand.
- Boston Orthokeratology (oprifocon A) Shaping Lenses must be both cleaned and disinfected each time you remove them. One procedure does not replace the other. Cleaning is necessary to remove mucus and film from the lens surface. Disinfecting is necessary to destroy harmful germs. To minimize lens warpage during cleaning, the lenses should be cleaned in the palm of the hand rather than between the thumb and fingers.
- Clean one lens first. The recommended procedure is to always clean the same lens first to avoid mix-ups. Rinse the lens thoroughly to remove the cleaning solution. Place the lens into the correct storage chamber and fill the chamber with the recommended disinfecting solution as recommended by your eye care practitioner. Clean and rinse the other lens in the same manner and place it in its chamber.
- Tightly close the top of each chamber of the lens storage case.
- To disinfect your lenses, leave them in the solution for at least the period indicated on the product label.
- Leave the lenses in the closed storage case until you are ready to put them in your eye.

## LENS CASE CLEANING AND MAINTENANCE

Contact lens cases can be a source of bacteria growth. Lens cases should be emptied, cleaned, rinsed with solutions recommended by the case manufacturer, and allowed to air dry. Lens cases should be replaced at regular intervals as recommended by the eye care practitioner.

## ENZYME CLEANING

The eye care practitioner may recommend enzyme cleaning. Enzyme cleaning does not replace routine cleaning and disinfecting. The patient should carefully follow the instructions in the enzymatic cleaning labeling.

## EMERGENCIES

If chemicals of any kind (household products, gardening solutions, laboratory chemicals, etc.) are splashed into the eyes, the patient should flush eyes immediately with tap water and then remove lenses promptly. The patient should CONTACT THE EYE CARE PRACTITIONER OR VISIT A HOSPITAL EMERGENCY ROOM WITHOUT DELAY.

## HOW SUPPLIED

Each lens is supplied non-sterile in an individual plastic case. The case, packing slip or invoice is marked with the base curve, power in diopters, diameter, center thickness, color, and Lot #.

## REPORTING OF ADVERSE REACTIONS:

All serious adverse experiences and adverse reactions observed in patients wearing or experienced with the lenses should be reported immediately to the manufacturer.

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